

REMARKS

The Applicants and the undersigned would like to thank the Examiner for Examiner's efforts in the examination of this application.

I. Election/Restriction

The Examiner has made a restriction requirement of the claims in the instant application. The previous office actions restricted the claims into two groups I (Claims 1-1) and II (Claims 18-20). It appears that typographical errors have been made in identifying the claims of the groups. Therefore, for the purposes of this office action the Applicants presume that the Examiner intended to restrict the claims as follows: Group I (Claims 1-16) and Group II (claims 17-20). The Applicants hereby elect examination of Group I (Claims 1-16) without traverse.

II. Specification

The Examiner objected to page 8 of the specification, stating that "the plurality of sensors 12 " is not consistent with "sensing system" of claim 1. The Applicants have amended "sensing system" in the claims of the instant application to read "sensing elements".

III. Rejection of claims 1-4 and 9-16 under 35 USC 102(b)

The Applicants have amended the claim 9 to depend from claim 7 to better present the claimed invention.

The Examiner has rejected claims 1-4 and 9-16 under 35 USC 102(b) as being anticipated by Johnson (US 3,866,599).

Independent claim 1 has been amended to more clearly present the features of the claimed invention.

Independent claim 1 as amended now recites: A surgical drain for sensing a physiological property of tissue and draining fluid from a body comprising:

a) an elongated conduit configured to be implanted in a patient's body and rest against a first tissue and a second tissue within the body to drain fluid from a ~~body cavity~~ the patient's body, wherein the elongated conduit ~~including a first surface located on an outer side of the elongated conduit and a second surface located on an outer side of the elongated conduit that is substantially opposite of the first surface;~~ comprises a drain portion having openings spaced along substantially the length of the drain portion; b) a first sensing system element configured to sense a physiological property of the first tissue ~~proximate to the first surface~~ adjacent to a first location of the elongated conduit; and c) a second sensing system element configured to sense the same physiological property of the second tissue adjacent to a second location of the elongated conduit different than the first location. ~~proximate to the second surface.~~

Johnson has disclosed an intravascular diagnostic catheter [1,2] with multiple optical fibers that work as a single transmit-receive system [7] from a single location (i.e. the recess 13, 23, 29, 35) at the distal tip of the catheter.

Intravascular diagnostic catheters are inserted into blood vessels (usually veins) and typically pushed all the way to the heart or the lungs to measure blood pressure, flow (cardiac output), oxygenation, and take blood samples for analysis. By their nature intravascular diagnostic catheter cannot be used to drain fluids because if so, they would be only draining blood out of the blood vessels leading to possible death. Also, in some embodiments Johnson discloses hydraulic transmission of a pressure signal to the outside, and in other embodiments (Fig 8 and Fig 11) pumping in air to inflate a balloon at the tip of the catheter.

On the other hand, the surgical drain of the present application is structurally different than Johnson's since claim 1 as amended now recites a

drain portion having openings spaced along substantially the length of the drain portion. As cited in the previous office action, the Examiner acknowledged that Johnson does not teach a plurality of drain holes of the present surgical drain. Also, Johnson does not teach a device that is configured to sense the same physiological property of tissue using first and second sensing elements at different locations of tissue. In claim 1 of the present application, the sensing elements are positioned at different locations of the elongated conduit so that one area of tissue sensed by one sensing element is not sensed by the other sensing element.

Therefore, claim 1 is allowable for the reasons above, and dependent claims 2-4 and 9-16 are allowable for the same reasons.

IV. **Rejection of claims 5-8 under 35 USC 103(a)**

The Examiner rejected claim 5 (now cancelled and incorporated into independent claim 1 as amended) as being obvious over Johnson in view of Russo. Dependent claim 5 has been cancelled and incorporated into amended claim 1. While Russo et al. (US 4,317,452) teaches a surgical drain to drain body fluids, Russo fails to teach the sensing elements of claim 1, and combination of Johnson and Russo is improper. The Examiner fails to establish the *prima facie* case of obviousness. (See MPEP 2142):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter,

either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections.

When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). A statement of a rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the examiner procedurally fails to establish a *prima facie* case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Rejection based on nine references which included at least 40 prior art rejections without explaining any one rejection with reasonable specificity was reversed as procedurally failing to establish a *prima facie* case of obviousness.).

The Examiner asserts "one would be motivated to modify the surgical drain of Johnson with drain holes of Russo to provide a means to drain body fluids and since both references disclose surgical drains for insertion into the body proximate tissue. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical drain, thus providing a plurality of drain holes." However, the Examiner fails to suggest **why** one of ordinary skill in the art would make such a combination or that there would be a reasonable expectation of success. Therefore, claim 5, now cancelled and incorporated into independent claim 1, is allowable over Johnson in view of Russo et al. because there is no suggestion by any one of the references to motivate one of ordinary skill in the art to combine them.

Examiner rejected claim 6 over Johnson in view of Harautuneian et al. (US 4,684,694), Koehn (US 3,030,953), Santomieri (US 3,515,137), and Beck (US 3,537,451). Koehn (US 3,030,953), Santomieri (US 3,515,137), and Beck (US 3,537,451) do not remedy the deficiencies of Johnson failing to teach a drain portion having openings spaced along substantially the length of the drain portion. The reference Examiner made to Harautuneian et al. having US patent number 4,684,694 is not valid and the prior art cited by the Examiner was not

found. However, the Applicants performed a patent search and located U.S. Patent number 3,989,571 to Harautuneian, which also fails to remedy the deficiencies of Johnson, as discussed above. Therefore, claim 6 is allowable.

Examiner rejects claim 7 over Johnson in view of Sadowski (US 3,614,737).

Sadowski fails to teach newly added limitation of the claim, namely a drain portion having openings spaced along substantially the length of the drain portion, and there is no motivation as why would one of ordinary skilled person in the art would combine the individual recognition system of Sadowski (apparatus for determining or verifying the identity of an individual wherein characteristics of a designated skin area of the individual for example on the hand, are transduced into electrical signals which are then matched to or compared with a corresponding set of stored electrical signals) with Johnson. Once again the burden of establishing a *prima facie* case has not been met by the Examiner as discussed above with respect to claim 5. Johnson never discusses a need for comparison means for its physiological property sensing system. Therefore, there is no motivation as why one of ordinary skill in the art would combine the comparison system of Sadowski with Johnson's catheter system.

Therefore, claim 7 is allowable over Johnson in view of Sadowski.

The Applicants have changed the word "temperature" in claim 8 to read "oxygenation." This amendment does not present new matter; support for this amendment is found in paragraph 54 of the specification.

The Examiner rejected claim 8 over Johnson in view of Sadowski and further in view of Leist (US 4,432,365). As discussed above with respect to claim 7, there is no motivation shown to combine Johnson and Sadowski, and therefore Leist does not remedy the lack of motivation to combine the references to come up with the present invention.

Therefore, claim 8 is allowable over Johnson in view of Sadowski and Leist.

I. Conclusion

Applicant respectfully submits that the above amendments place this application in a condition for allowance, which Applicant respectfully solicits the same. The Applicant and the undersigned would like to again thank the examiner for her efforts in the examination of this application and for reconsideration of the claims as amended in light of the arguments presented. If the further prosecution of the application can be facilitated through an interview between the Examiner and the undersigned, the Examiner is requested to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,
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